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Regulatory Directive DIR2013-04

Pesticide Resistance Management Labelling Based on Target Site/Mode of Action

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1.0 Preface

This is an update to the Pest Management Regulatory Agency's (PMRA) pesticide resistance-management labelling initiative based on target site/mode of action for agricultural uses of herbicides, fungicides/bactericides and insecticides/acaricides. This document provides a standard format for showing group identification symbols on the end-use product labels, and guidelines for labelling resistance-management strategies in the use directions. It covers both new and existing products governed by the registration process.

This document replaces Regulatory Proposal PRO99-06, *Voluntary Pesticide Resistance Management Labelling Based on Target Site/Mode of Action,* published in October 1999.

Canada and the United States, working cooperatively under the auspices of the North American Free Trade Agreement (NAFTA), are developing and publishing these guidelines for voluntary pesticide resistance-management labelling to a uniform standard for implementation in North America. A uniform approach across North America may help delay the development of pesticide resistance and support joint registration decisions by providing consistency in the resistance-management labelling being considered for approval in any or all of the NAFTA countries.

2.0 Scope

This Regulatory Proposal applies to resistance-management labelling for herbicide, fungicide/bactericide and insecticide/acaricide products that are intended for general agricultural use. This document applies to both new products that are being registered as well as existing, currently registered products.

Participation in this program is on a voluntary basis. However, registrants are encouraged to add the resistance-management grouping symbols and statements to both new and existing product labels. Revisions to labels for existing products can be made at the next printing of the labels. Information on amending labels can be obtained from the PMRA Information Service at 1-800-267-6315 (toll-free within Canada) or 613-736-3799. In view of the importance of resistance management to a sustainable pest-management system, the PMRA closely monitors the progress of the industry's implementation of resistance-management labelling.

Canada, the United States and Mexico are committed to encouraging the development of sustainable pest-management systems. Under the auspices of NAFTA, Canada and the United States have joined together to develop and publish guidelines for voluntary pesticide resistance-management labelling for implementation in their respective countries. The guideline initiative has also been discussed with Mexico's Comisión Federal para la Protectión contra Ríesgos Sanitarios (COFEPRIS) and Secretaría de Agricultura, Ganadería, Desarollo Rural, Pesca y Alimentacion (SAGARPA), the two federal agencies charged with developing and implementing pesticide labels in that country. While these discussions are at a preliminary stage, a uniform approach across North America will help delay the development of pesticide resistance and support joint registration decisions by providing consistency in resistance-management labelling being considered for approval in any or all of the NAFTA countries.

This Regulatory Directive describes the format for including important resistance management information on pesticide labels. This is part of a NAFTA labelling harmonization effort on pesticide resistance management.

3.0 Introduction

Many pesticides registered in Canada contain resistance management statements on their labels. This indicates that registrants understand the value of this information to pesticide users and how it could contribute to delaying the development of pest resistance. However, as new developments unfold in the field of resistance management, there is a need to ensure that the conditions of use stated on product labels continue to play a positive role in reducing the risk of resistance development.

Pesticide resistance, which can be defined as a heritable and significant decrease in the sensitivity of a pest population to a pesticide, reduces the field performance of pesticides. Pests include insects, mites, weeds, fungi and bacteria. The management of pesticide resistance development is an important part of sustainable pest-management and this, in conjunction with alternative pest-management strategies and integrated pest-management (IPM) programmes, can make significant contributions to reducing risks to humans and the environment from pesticide use. In support of this goal, the purpose of this document is to provide guidance on resistance-management labelling to registrants.

Pesticides are important pest-management tools. Many pesticides have gradually lost their effectiveness due to the development of resistance by pests. An important proactive pesticide resistance-management strategy is to avoid the repeated use of a particular pesticide, or pesticides, that have a similar site of action, in the same field, by rotating pesticides with different sites of action. This approach may delay the development of one important type of resistance, target-site resistance, without resorting to increased rates and frequency of application, and may prolong the useful life of pesticides.

A resistance-management strategy should also consider more detailed information regarding cross-resistance between pesticides with different modes of action resulting from the development of other types of resistance (for example, enhanced metabolism, reduced penetration, or behaviour changes). All members of a class may not be cross-resistant based merely on site of action. However, this labelling initiative will provide pesticide users with easy access to important information regarding target-site resistance, the cornerstone of most resistance-management programs.

To ensure consistency in pesticide grouping and labelling, and to contribute to the management of pesticide resistance, the following guidelines have been developed for agricultural uses of herbicides, fungicides/bactericides and insecticides/acaricides. The classification schemes shown in Section 4.0 are based on target site/mode of action.

The PMRA considers resistance management during the review process. In addition to the Mode of Action/Target Site classification and general resistance management statements (Sections 4.0 and 5.0), product-specific statements relating to resistance management are added to product labels. These statements provide guidance on how to maintain long-term pesticide performance as well as indicate to users how they should use a pesticide product in order to delay resistance development. For example, restrictions on the number of applications per season or the number of sequential applications may be included.

The PMRA believes that this approach supports sustainable agriculture by providing the best possible guidance to pesticide users to reduce the likelihood of resistance developing in target pest populations in their localities. With the cooperation of registrants, the PMRA will continue to implement these strategies in order to mitigate the risks for resistance development.

4.0 Site of Action Grouping and Identification Symbol

Herbicides, fungicides/bactericides and insecticides/acaricides are separately grouped according to their site of action by various technical/research committees consisting of representatives of the pesticide industry, researchers, extension specialists and regulatory officials The PMRA implements guidance on the pesticide groupings provided by the Weed Science Society of America (WSSA; http://www.wssa.net/), the Herbicide Resistance Action Committee (HRAC; http://www.hracglobal.com/), the Fungicide Resistance Action Committee (FRAC; http://www.frac.info/) and the Insecticide Resistance Action Committee (IRAC; http://www.irac-online.org/). The site of action groups plus the identifier numbers for herbicides, fungicides/bactericides and insecticides/acaricides may be accessed through the websites of these organizations.

The site of action identification number or symbol should be shown on herbicide, fungicide and insecticide end-use product labels intended for general agricultural use in a standard format as outlined below, and should:

- be located on the front panel (preferably at the upper right corner), surrounded by a black rectangle;
- be in black on a white background except the site of action number(s), which is to be white on a black background with a clear white gap between the site of action number(s); and
- include the words "GROUP" and "HERBICIDE" or "FUNGICIDE" or "INSECTICIDE" in capital letters, and between these words the number(s) representing the site of action group(s) of each active ingredient(s). Where a product has two or more active ingredients, and these are represented by two or more sites of action, then two or more appropriate site of action identifier numbers should be used. For products containing an active ingredient that has multiple sites of action, specify each site of action by the appropriate designation.

Example 1: Product containing one or more active ingredients of the same site of action.

GROUP	1	HERBICIDE

Example 2: Product containing two or more active ingredients represented by two or more sites of action.

GROUP	1 | 2 | 3	HERBICIDES

Example 3: Outside label for prepackaged products where each component is in a different container.

GROUP	1	HERBICIDE

GROUP	2	HERBICIDE

Example 4: Pre-mixture of a fungicide and an insecticide.

GROUP	1	FUNGICIDE
GROUP	2	INSECTICIDE

5.0 Resistance-Management Statements

Resistance-management statements are recommended to be included in the use directions for all end-use products for the control of weeds, plant pathogens (diseases), insects and arthropods (except products for homeowner/residential uses) under the heading "Resistance-Management Recommendations". The section "Resistance-Management Recommendations" should be segregated under the "General" portion of "Use Directions" in the United States, and under "Use Directions" in Canada. Product-specific labelling is recommended. The recommended standard resistance-management labelling statements listed below focus on the prevention and mitigation of pest resistance and should be used where applicable. Efforts should be made to include all appropriate active ingredients and products. These recommendations should also be included in any product-specific literature.

5.1 Herbicides

For resistance management, (name of product) is a Group (site of action group number) herbicide. Any weed population may contain or develop plants naturally resistant to (name of product) and other Group (site of action group number) herbicides. The resistant biotypes may dominate the weed population if these herbicides are used repeatedly in the same field. Other resistance mechanisms that are not linked to site of action, but specific for individual chemicals, such as enhanced metabolism, may also exist. Appropriate resistance-management strategies should be followed.

To delay herbicide resistance:

- Where possible, rotate the use of (name of product) or other Group (site of action group number) herbicides within a growing season (sequence) or among growing seasons with different herbicide groups that control the same weeds in a field.

- Use tank mixtures with herbicides from a different group when such use is permitted. To delay resistance, the less resistance-prone partner should control the target weed(s) as effectively as the more resistance-prone partner.

- Herbicide use should be based on an integrated weed management program that includes scouting, historical information related to herbicide use and crop rotation, and considers tillage (or other mechanical control methods), cultural (for example, higher crop seeding rates; precision fertilizer application method and timing to favour the crop and not the weeds), biological (weed-competitive crops or varieties) and other management practices.

- Monitor weed populations after herbicide application for signs of resistance development (for example, only one weed species on the herbicide label not controlled). If resistance is suspected, prevent weed seed production in the affected area if possible by an alternative herbicide from a different group. Prevent movement of resistant weed seeds to other fields by cleaning harvesting and tillage equipment when moving between fields, and planting clean seed.

- Have suspected resistant weed seeds tested by a qualified laboratory to confirm resistance and identify alternative herbicide options.

- Contact your local extension specialist or certified crop advisors for any additional pesticide resistance-management and/or integrated weed-management recommendations for specific crops and weed biotypes.

- For further information or to report suspected resistance, contact (company representatives) at (toll free number) or at (Internet site).

NOTE The above is a standard statement for products containing one or more active ingredients from the same group. For products containing two or more active ingredients from different groups, the statement should be modified to reflect the situation.

For example:

For resistance management, please note that (name of product) is both a Group (site of action group number) and a Group (site of action group number) herbicide. Any weed population may contain plants naturally resistant to Group (site of action group number) and/or Group (site of action group number) herbicides. The resistant biotypes may dominate the weed population if these herbicides are used repeatedly in the same fields.

5.2 Fungicides and Bactericides

For resistance management, (name of product) contains a Group (site of action group number) (fungicide/bactericide). Any (fungal/bacterial) population may contain individuals naturally resistant to (name of product) and other Group (site of action group number) (fungicides/bactericides). A gradual or total loss of pest control may occur over time if these (fungicides/bactericides) are used repeatedly in the same fields. Other resistance mechanisms that are not linked to site of action but specific for individual chemicals, such as enhanced metabolism, may also exist. Appropriate resistance-management strategies should be followed.

To delay fungicide/bactericide resistance:

- Where possible, rotate the use of (name of product) or other Group (site of action group number) fungicides/bactericides with different groups that control the same pathogens.

NOTE This statement may be modified if repeated application is necessary, for example, Avoid application of more than (maximum number) and consecutive sprays of (name of product) or other (fungicides/bactericides) in the same group in a season.

- Use tank mixtures with fungicide/bactericides from a different group that is effective on the target pathogen when such use is permitted.

- Fungicide/bactericide use should be based on an integrated disease management program that includes scouting, historical information related to pesticide use and crop rotation and considers host plant resistance, impact of environmental conditions on disease development, disease thresholds, as well as cultural, biological and other chemical control practices.

- Where possible, make use of predictive disease models to effectively time fungicide/bactericide applications.

- Monitor treated fungal/bacterial populations for resistance development. Notify (company name) if reduced sensitivity of the pathogen to (product name) is suspected.

If disease continues to progress after treatment with this product, do not increase the use rate. Discontinue use of this product, and switch to another (fungicide/bactericide) with a different site of action, if available.

- Contact your local extension specialist or certified crop advisors for any additional pesticide resistance-management and/or IPM recommendations for specific crops and pathogens.

For further information and to report suspected resistance, contact (company representatives) at (toll free number) or at (Internet site).

NOTE The above is a standard statement for products containing one or more active ingredients from the same group. For products containing two or more active ingredients from different groups, the statement should be modified to reflect the situation.

For example:

For resistance management, please note that (name of product) contains both a Group (site of action group number) and Group (site of action group number) fungicide/bactericide. Any fungal/bacterial population may contain individuals naturally resistant to (name of product) and other Group (site of action group number) or Group (site of action group number) fungicides/bactericides. A gradual or total loss of pest control may occur over time if these (fungicides/bactericides) are used repeatedly in the same fields.

5.3 Insecticides and Acaricides

For resistance management, (name of product) contains a Group (site of action group number) insecticide (or acaricide). Any (insect/mite) population may contain individuals naturally resistant to (name of product) and other Group (site of action group number) (insecticides/acaricides). The resistant individuals may dominate the insect/mite population if this group of insecticides/acaricides is used repeatedly in the same fields. Other resistance mechanisms that are not linked to site of action but are specific for individual chemicals, such as enhanced metabolism, may also exist. Appropriate resistance-management strategies should be followed.

To delay insecticide resistance:

- Where possible, rotate the use of (name of product) or other Group (site of action group number) insecticides/acaricides with different groups that control the same pests.

NOTE The above statement may be modified on a pest-by-pest basis if a number of applications each year are necessary, for example, Avoid application of more than (maximum number) and consecutive sprays of (name of product) or other insecticides in the same group in a season.

- Use tank mixtures with insecticides/acaricides from a different group that is effective on the target pest when such use is permitted.

- Insecticide/acaricide use should be based on an IPM program that includes scouting and record keeping, and considers cultural, biological and other chemical control practices.

- Monitor treated pest populations for resistance development.

- Contact your local extension specialist or certified crop advisors for any additional pesticide resistance-management and/or IPM recommendations for the specific site and pest problems in your area.

- For further information or to report suspected resistance contact (company representatives) at (toll free number) or at (Internet site).

NOTE The above is a standard statement for products containing one or more active ingredients from the same group. For products containing two or more active ingredients from different groups, the statement should be modified to reflect the situation.

For example:

For resistance management, please note that (name of product) contains both a Group (site of action group number) and Group (site of action group number) insecticides/acaricides. Any insect/mite population may contain individuals naturally resistant to (name of product) and other Group (site of action group number) or Group (site of action group number) insecticides/ acaricides. The resistant individuals may dominate the insect/mite population if these insecticides/acaricides are used repeatedly in the same fields.

6.0 Pesticides of Unspecified Groups

Some herbicides, fungicides, bactericides, insecticides and acaricides have not been assigned to any particular site of action group because of the lack of clear understanding of their target site/mode of action or the absence of a history of resistance development for the product. Registrants should establish the appropriate site of action group identifications for their products in consultation with representatives of the pesticide industry, technical working groups such as IRAC, HRAC, and FRAC, researchers, extension specialists and regulatory officials, if appropriate. The use directions should include the appropriate resistance-management statements for the product, i.e. herbicides, fungicides/ bactericides and insecticides/acaricides.

The pesticide classification schemes are updated from time to time to include new active ingredients and/or new/revised site of action classification. Information regarding new or revised site of action classification may be obtained from the websites of the organizations identified in Section 4.0.

7.0 Implementation

PMRA will permit registrants to add the standard resistance management labelling statements and the target site/mode of action classification to product labels by notification. Amendments to standard label statements based on specific use patterns will require an application to the PMRA and will be evaluated during the value assessment.

Appendix I – Comment and Response

The PMRA received comment in response to Regulatory Proposal PRO2012-02, *Pesticide Resistance Management Labelling Based on Target Site/Mode of Action*, from a stakeholder. It is summarized below.

1.0 Comment relating to the voluntary nature of the proposal

The voluntary nature of the proposal is important to ensure the ability to modify the standard labelling statements when required, as they pertain to specific uses and in consideration of input from resistance management experts.

PMRA Response

The standard resistance management label statements may be modified to reflect recommendations to reduce resistance risk relative to the supported use pattern through an application to the PMRA. During the value assessment, the PMRA considers recommendations from the resistance action committees as well as advice from resistance management experts. The PMRA will continue to work with registrants and other stakeholders in the adoption of these label statements in order to reduce the overall risk for resistance development.

2.0 Comment relating to the addition of standard statements to product labels

The addition of the standard statements to product labels should be done by Notification/Non-notification in order to mitigate the need for additional PMRA resources. However, if product-specific or customized statements are needed, a PMRA review should be conducted.

PMRA Response

The addition of standard resistance management label statements to pesticide product labels may be done by notification consistent with current practice. Modifications to standard statements based on specific use patterns should be proposed in an application to the PMRA and will be subject to a value assessment.

3.0 Comment relating to consultation with resistance management experts

In addition to recommendations from resistance action committees, PMRA should also take into consideration the advice from Canadian resistance management experts including scientists, extension staff and others who work closely with pesticide users.

PMRA Response

In the revision of Regulatory Directive 1999-06, *Voluntary Pesticide Resistance Management Labelling Based on Target Site/Mode of Action*, the PMRA consulted with the Canadian Weed Science Society, the Canadian Phytopathological Society and the Entomological Society of Canada to ensure that the standard resistance management statements are reflective of current recommendations. PMRA also worked closely with USEPA to ensure consistency in approach in the two countries.

During the value assessment, updated recommendations on resistance management relating to a particular crop/site-pest combination are considered in the decision regarding the final supported use pattern. In addition to considering information from the resistance action committees, PMRA consults with Canadian resistance management experts and provincial crop specialists in order to identify the most appropriate approach to resistance management.

4.0 Comment regarding consistency in resistance management approach

PMRA should work closely with the United States and Mexico to ensure the quality and consistency of pesticide resistance management labelling whenever possible.

PMRA Response

The PMRA worked closely with USEPA in the revision of the guidance documents to ensure consistency in approach by both countries. Mexico was involved in the discussions as well and Canada will continue to work with the United States and Mexico towards a common approach for North America.